B1

influencing the aspect ratio of said ice crystals are one or more conditions selected from the group consisting of: rate of freezing, mobility of the product during freezing, storage temperature, storage, formulation of the product and nature and amount of anti-freeze peptides such that the ice-crystals in the product have an aspect ratio more than 1.9.

In claim 9, change the letters "AFP" to the phrase --anti-freeze peptides--.

Please cancel claim 3.

#### **REMARKS**

Re-examination of the claims and reconsideration of the Examiner's rejections is requested in view of the foregoing amendments and the following remarks.

Applicants have rewritten the claims with a process step and to the extent the claims were indefinite for not having a process step, they are now believed to be definite within the ambit of 35 U.S.C. §112 paragraph 2.

Applicants have included a terminal disclaimer over Serial Number 08/890,453 to overcome the Examiner's provisional rejection under 35 U.S.C. §103(a).

Applicants request reexamination and withdrawal of the Examiner's rejection under 35 U.S.C. §103(a) over Clemmings, Fletcher or Warren, each in view of WO 92/25281 and applicants' alleged admission.

Applicants have made no admission other than explaining the text of WO 92/22581. This publication in several places states that:

"some...polypeptides are antifreeze components which control ice crystal growth in extracellular spaces..." and

"that... one or more of the polypeptides...provide a...product having minute crystalline structure"

#### The present invention

The present invention as claimed generally

- relates to a process to make frozen food products having ice crystals
- b. comprising incorporating anti-freeze proteins
- c. conditions of making are chosen such that the ice-crystals have an aspect ratio of more than 1.9
- d. the inherent property that product with this aspect ratio has an advantageous combination of properties, especially textural properties (see page 5, lines 4-11 of the specification).

#### Clemmings

# Differences between the Art Cited and the Invention:

Clemmings discloses a method for preparing an ice-cream comprising the addition of an anti-freeze protein followed by storage at relatively high temperatures Clemmings does not explicitly teach elements c. or d. of applicants' invention.

Applicants submit that Clemmings does not inherently disclose these features. In particular, Clemmings does not specify in its examples which AFPs are used and also the conditions for making are only generally described as being "conventional". Therefore, the difference between the present invention and Clemmings is two-fold. Clemmings has not recognized that the textural properties of an AFP containing frozen food are a function of the aspect ratio of its ice-crystals (compare In Re Antonie, 559 F.2d 618,195 USPQ 6,8(CCPA 1977)).

Applicants do not admit that the aspect ratio is a "result effective variable", but clearly to the extent that the aspect ratio could be considered a "result effective variable", it is certainly not a <u>recognized</u> "result effective variable". Further, Clemmings has not disclosed any specific combination of processing conditions and choice of AFP which would lead the skilled person to make frozen food products having an aspect ratio of more than 1.9.

## The Level of Ordinary Skill in the Art

It is generally known, e.g., from WO 92/22581, that anti-freeze proteins may change the size of ice-crystals.

What is not generally known is that the textural properties of frozen confectionery products with AFPs depend upon the aspect ratio of the crystals in the product.

There is no prima facie case of obviousness over Clemmings in view of the ordinary skill exemplified in WO 92/22581. The references taken together would not motivate the skilled person to change the teaching of Clemmings to arrive at features c. and d. of the invention. In order to have a prima facie case of obviousness, three criteria must be satisfied:

- 1. A suggestion or motivation either in the references themselves or the knowledge generally available to modify the reference or to combine the teaching. This motivation is lacking in Clemmings or WO 92/22581. Clemmings is aimed at the minimization of ice-crystals (see summary of invention) and not specifically at influencing the ice-crystal shape to get different textural properties.
- 2. A reasonable expectation of success. Although it was known that AFPs could influence the shape of ice-crystals, applicants submit that there was no reasonable expectation of success. The state of the art had not recognized that the textural properties of an AFP containing frozen food are a function of the aspect ratio of its ice-

crystals. Therefore, a skilled person desiring to change the textural properties of a frozen food product with AFP would, in the absence of this functional understanding, not have a reasonable expectation of success. There is absolutely no recognition that the aspect ratio is critical.

3. The prior art references must suggest all of the claim limitations. Applicants submit that this is not satisfied because neither Clemmings nor WO 92/22581 teach the specific aspect ratio of more than 1.9, nor the functional relationship between aspect ratio and textural properties.

In conclusion, there are significant differences between Clemmings and the claimed invention. No case of prima facie obviousness exists based on Clemmings in view of WO 92/22581 primarily because the requirements of a prima facie obviousness case are not satisfied.

#### Fletcher

## Differences between the art cited and the invention

Fletcher relates to methods for the preparation of frozen fermented food products using fish anti-freeze polypeptides expressing microorganisms.

Fletcher does not explicitly teach c. or d. of applicants' invention.

Applicants submit that Fletcher does not inherently disclose these features. In particular, Fletcher only provides general guidelines of broad classes of anti-freeze proteins which may be used (column 4, line 58, etc.) and broad possibilities for processing conditions (column 6, line 21, etc.)

Therefore, the difference between the present invention and Fletcher is two-fold. Fletcher has not recognized that the textural properties of an AFP containing frozen food are a function of the aspect ratio of its ice-crystals (compare In Re Antonie above).

And also Fletcher has not disclosed any specific combination of processing conditions and choice of AFP which would lead the skilled person to the making of frozen food products having an aspect ratio of more than 1.9.

### The Level of Ordinary Skill in the Art

It is generally known, e.g., from WO 92/22581, that anti-freeze proteins may change the size of ice-crystals.

What is not generally known is that the textural properties of frozen confectionery products with AFPs depend upon the aspect ratio of the ice crystals in the product.

There is no prima facie case of obviousness over Fletcher in view of ordinary skill exemplified in WO 92/22581. As stated above, three criteria must be satisfied.

- 1. A suggestion or motivation either in the references themselves or the knowledge generally available to modify the reference or to combine the teaching. This motivation is lacking in Fletcher. Fletcher is aimed at maintaining the quality of frozen food products during storage (see summary of invention) and not specifically at influencing the ice-crystal shape to get different textural properties.
- 2. A reasonable expectation of success. Although it was known that AFPs could influence the shape of ice-crystals, applicants submit that there was no reasonable expectation of success. The state of the art had not recognized that the textural properties of an AFP containing frozen food are a function of the aspect ratio of its ice-crystals. Therefore, a skilled person desiring to change the textural properties of a frozen food product with AFP would, in the absence of this functional understanding, not have a reasonable expectation of success.
- 3. The prior art references must suggest the claim limitations. Applicants submit that this is not satisfied because neither Fletcher nor WO 92/22581 teach the specific

aspect ratio of more than 1.9, nor the functional relationship between aspect ratio and textural properties.

In conclusion there are significant differences between Fletcher and the claimed invention. No case of prima facie obviousness can be established based on Fletcher in view of WO 92/22581 because the requirements of a prima facie obviousness case are not satisfied.

#### Warren

## Differences between the Cited Art and the Invention

Warren relates to methods of improving the freezing tolerance of foodstuffs or biologic materials through the use of antifreeze polypeptides (see summary of invention).

Warren does not explicitly teach c. or d. of applicants' invention.

Applicants submit that Warren does not inherently disclose these features. In particular, Warren discloses fusion proteins which can have a wide range of compositions. Furthermore, Warren does not provide examples of suitable processing conditions. Therefore, the difference between the present invention and Warren is two-fold. Warren has not recognized that the textural properties of an AFP containing frozen food are a function of the aspect ratio of its ice-crystals (compare In Re Antonie above). And also Warren has not disclosed any specific combination of processing conditions and choice of AFP which would lead the skilled person to the making of frozen food products having an aspect ratio of more than 1.9.

## The Level of Ordinary Skill in the Art

It is generally known from WO 92/22581 that anti-freeze proteins may change the size of ice-crystals.

What is not generally known is that the textural properties of frozen confectionery products with AFPs depend upon the aspect ratio of the crystals in the product.

There is no prima facie case of obviousness over Warren in view of ordinary skill exemplified in WO 92/2258. As stated above, three criteria must be satisfied.

- 1. A suggestion or motivation either in the references themselves or the knowledge generally available to modify the reference or to combine the teaching. This is lacking in Warren. Warren is aimed at maintaining the quality of frozen food products during storage (see summary of invention) and not at influencing the ice-crystal shape to get different textural properties
- 2. A reasonable expectation of success. Although it was known that AFPs could influence the shape of ice-crystals, applicants submit that there was no reasonable expectation of success. The state of the art had not recognized that the textural properties of an AFP containing frozen food are a function of the aspect ratio of its ice-crystals. Therefore, a skilled person desiring to change the textural properties of a frozen food product with AFP would, in the absence of this functional understanding, not have a reasonable expectation of success.
  - 3. The prior art references must suggest all of the claim limitations. Applicants submit that this is not satisfied because neither Warren nor WO 92/22581 teach the specific aspect ratio of more than 1.9, nor the functional relationship between aspect ratio and textural properties.

In conclusion, there are significant differences between Warren and the claimed invention. No case of prima facie obviousness can be established based on Warren in view of WO 92/22581 because the requirements of a prima facie case of obviousness case are not satisfied.

In light of the foregoing amendment and remarks, early favorable action is solicited.

If a telephone conversation would be of assistance in advancing the prosecution of the present application, applicants' undersigned attorney invites the Examiner to telephone at the number provided.

Respectfully submitted,

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